Derek Edgar

Exhibit 35

VF 12-12-18

Welcome to Biomet!

Metal-On-Metal Articulations: *Fact v. Fiction*

Derek Edgar, Product Manager

Why Metal-on-Metal?

- **POLY** continues to be the weak link in THR
- **Patients** demand better performance
  - Almost 20% of THR patients are ≤ **55 years!**

Metal-On-Metal is Mature Technology

- Sivash - 1959
  - 28 mm
- Ring - 1964
  - 40mm
- Müller - 1965
  - 37 and 42mm
- McKee-Farrar - 1965
  - 38 and 41mm

...But M-O-M Was Abandoned With The Advent of Poly

- Resounding success of the Charnley M-PE design
- Early M-O-M loosening/frictional torque
- Carcinogenesis concerns
- Metal sensitivity concerns

Amstutz et al., *CORR* 1996

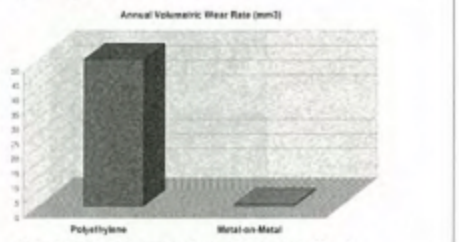
Metal-Metal Was An Idea Ahead Of Its Time

- First material was **stainless steel**
  - Philip Wiles, 1938, England
- Improper clearance
  - Components **hand-ground** and lap fit together
- Equatorial loading devices
  - **Design tolerances**
  - Roundness/Sphericity
- Surface finish
  - **.1 to 1 micron**

PLAINTIFF'S EXHIBIT 932 4:13-cv-800-SRC

Nevertheless, The 1960s Metal/Metal Hips Performed!

- Metal/metal devices with acceptable tolerances outperformed polyethylene by a wide margin.



Benign tissue reaction. No Metallosis.

...With Very Strong Clinical Results

Sivash Metal/Metal →

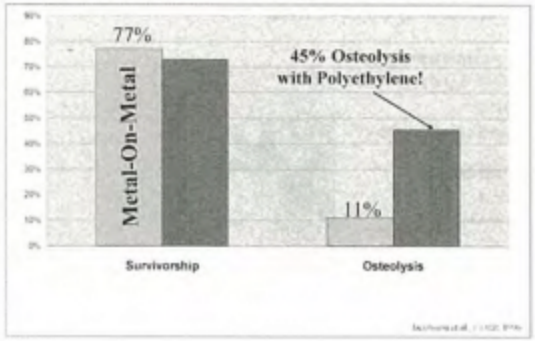
16-22 year follow-up study

- *NO* significant wear
  - 4 µm per year
- *NO* fretting
- *NO* corrosion
- *NO* adverse tissue response

McKee v. Charnley at 20 Years

Jacobsson et al., CJARR, 1996

McKee v. Charnley at 20 Years



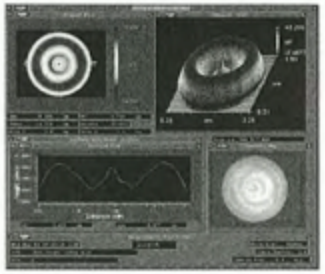
Metal/Metal Pioneers of the 1960s Taught Us 3 Important Lessons...

Metal/Metal constructs must have:

1. Extremely tight design **tolerances.**
2. Optimal materials and **manufacturing.**
3. Proper **head clearance.**

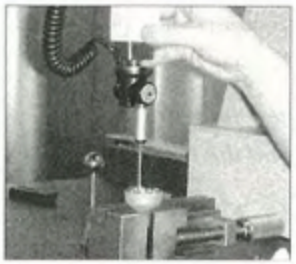
Today's Metal/Metal Designs

1. **Extremely tight design tolerances.**



Today's Metal/Metal Designs

2. Optimal Materials & Manufacturing Process



Today's Metal/Metal Designs

3. Optimal Head Clearance

- Characterized by **polar loading**
- Allows proper **fluid lubrication**
- **Low wear** and low frictional torque
- Room for **removal of** debris

Example: TOO MUCH Clearance

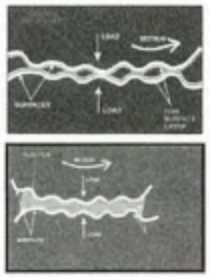
- Femoral head is considerably smaller than the liner
- Produces high contact stresses
- Disrupts fluid lubrication
- Leads to ↑ wear

Example: TOO LITTLE Clearance

- Equatorial contact
- ↑ chance of components locking together
- Creates high frictional torque
- Leads to early loosening and ↑ wear

Fluid Lubrication

- Boundary (First Generation M-M)
  - Load through asperity contacts
- Mixed Film (M^2a^{-1})
  - Load through both asperity contact and fluid film
- Fluid Film (Ideal Condition)
  - Load through full fluid film

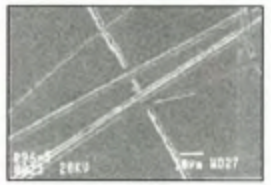


Chan et al., *LMOS* 1997

Metal/Metal Self-Polishes

Repairs surface damage

- Retrieval analysis
  - Scratches smoothed
- Prevents accelerated wear



McKellop et al. *5th World Bio Congress*, 1996

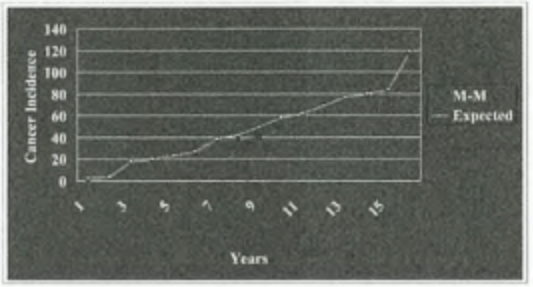
But What About CANCER???

Finnish Cancer Registry

- **579 patients** with McKee-Farrar M-M prostheses
  - **15.7** year average follow-up
- 1,585 patients with M-PE prosthesis
  - 12.5 year average follow-up
- Matched by age and sex

Visuri, *CORR* 1996

M-M Cancer Rates v. General Population



Other Notable Metal Ion/Cancer Studies

Tharani, et al., JBJS May 2001

- **Evaluated 9 studies, ranging from 6 months to 17 years**

"Available data do not support a causal link between THA and the development of cancer."

Adverse Biologic Responses?

Merritt, et al., CORR 1996

"...It is clear at this stage in total joint replacement, that more reported adverse biologic responses are occurring (due) to the polyethylene than to the metal"

More Metal Ion Studies…

Brodner et al., Clinical Toxicology 1999

"Toxic serum levels of cobalt after release from implants have not been observed, nor is there any evidence of cobalt-associated pathology…"

And More Metal Ion Studies…

Shaffer et al., Journal of Bone and Joint Surgery 1997
- Studied erythrocyte and urine levels

"Acute or chronic systemic intoxication (of Co and Cr) is not likely…"

"We conclude that the elimination of Co and Cr proceeds over several years, effecting a balance between release and excretion."

In Half a Century Of CoCr Implants…

There is <u>NO EVIDENCE</u> establishing a link between CANCER and ion release from CoCr implants.

Today's Metal/Metal Implants

- Sulzer Metasul™
  - Sandwich design
- Biomet M²a-Taper™
  - First all-metal design, May 2000
- DePuy Ultima™
- Encore Metal/Metal™
  - Sandwich design
- Wright Medical Transcend®

M²a™ Specifications

- Wrought CoCrMo
- Radial Clearance 25-75 µm
- Surface Finish .005-.009 µm
- Sphericity <5 µm
- Seven modular head options: -6, -3, STD, +3, +6, +9, +12mm

M²a-Taper™

- All Metal!
- 28mm cleared May 2000
  - Shell sizes 48-70mm
  - 126 degrees ROM
- 32mm cleared Sept. 2000
  - Shell sizes 52-70mm
  - 132 degrees ROM

Biomet's M²a-Taper™

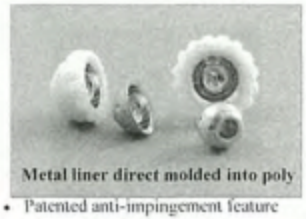
<u>2 Shell Options:</u>

- Universal® 2-hole
  - 17 degree rim flare
- Mallory-Head® 2-hole
  - Peripheral fins

Taper Design:

- Outer surface Ra 150µin
- 18 degree taper angle

M²a-Ringloc™



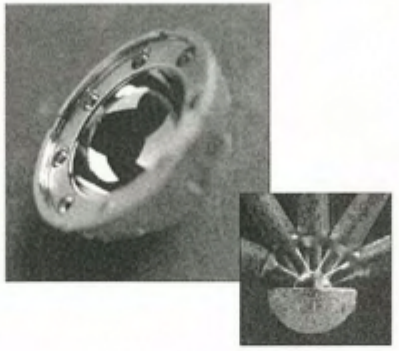
Metal liner direct molded into poly

- Patented anti-impingement feature
- Fits any full hemisphere RingLoc® shell
- Flat face and 10 degree option

Quality Control

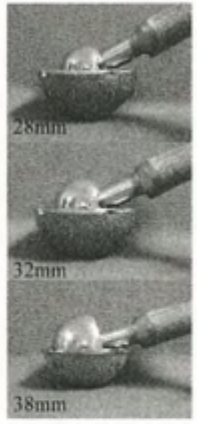
- 100% of devices
- Radius
  - CMM method
- Sphericity
  - Zygo system
- Surface Finish
  - Zygo system
  - Visual inspection

M²a-38™



M²a™-38

- 154° Range of Motion
- One piece cobalt chrome design, non-modular
- Ultra low .04mm³/10⁶ cycles steady state wear
- Available in sizes 48-70mm - big head in small acetabulums!



M²a™-38

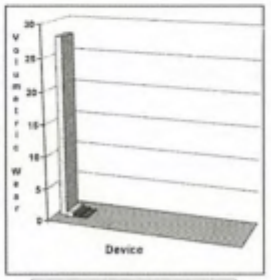
- 8 Rim screws start at size 56mm
- 4 Pairs of small peripheral fins, 17° rim flare, and porous plasma spray supply strong fixation
- Optimally designed shell maximizes ROM and minimizes prosthetic impingement
- Non-skirted head sizes -6mm through +9mm.

M²a™-38

- **Instruments Used:**
  - Face plate shell inserter
  - 38mm trial heads and shells
  - Metal-on-metal head impactor

M²a™ Wear Rates

- 28mm steady state wear
  - .73mm³
- 32mm steady state wear
  - .30mm³
- 38mm steady state wear
  - .12mm³
- ArCom® steady state wear
  - 27.9mm³
- 97-98% less volumetric wear than ArCom®



Testing and Validation

- Push out Strength
  - M^2a^{TM} Taper 612lbs
  - M^2a^{TM} RingLoc 1,200 lbs.
  - ArCom® RingLoc® 660 lbs.
- Fatigue Testing and Fretting
  - Cyclic loads of 1000 lbs. to 10 million cycles were applied
  - No fretting between head and liner observed visually
  - Material transfer < 1%

Clinical Results

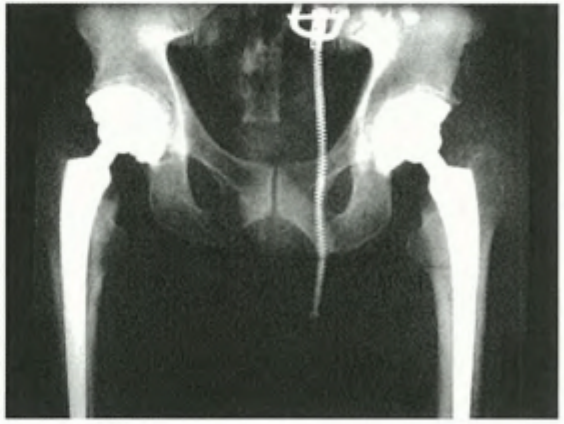
- Controlled Randomized Study
  - 8 Sites
  - 97 Patients each group
    - RingLoc® Shells/ ArCom®Poly
    - M^2a^{TM}-Taper
  - All Stems Cementless Fixation

M^2a^{TM}-Taper Clinical Results

- 97 Matched Pairs
- Average age 50.0
- Pre-operative HHS 51.6
- Post-operative HHS 95.23 at three-year post-op
- Average follow-up 3.6 years

M^2a^{TM}- Taper Clinical Results

- 97 patients > 2.0 years post-op
- 61 patients > 3.0 years post-op
- 37 patients > 4.0 years post-op
- 10 patients > 5.0 years post-op
- 3 dislocations less than 6 months follow-up
  - Closed reductions, all performing well clinically
- **NO REVISIONS**



In Conclusion…

1. Metal-Metal is **not new**!
2. There have been **NO REPORTS OF CANCER** related to CoCr implants
3. Patients are younger, more active
4. Wear rates **100 times less** than UHMWPE

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